REMARKS

The Office Action of August 30, 2010 has been carefully considered.

Subject matter headings have been added to the specification.

Claims 1-6 have been rejected under 35 USC 103(a) over Palasis et al in view of Webster, Jr. In addition, claims 7-15 have been rejected under 35 USC 103(a) over Palasis et al in view of Webster, Jr and further in view of Stawski.

Claims 1-15 have now been replaced by new claims 16-30, written in proper form for US practice.

The invention is directed to a needle used for injecting pharmaceuticals, which is made of plastic. In particular, the needle of the invention is made of a specific polyaryletherketone polymer having a formula (1) according to claim 16, and which may be sold under the trade name PEEK; the trade name will be used as shorthand for the polymer in these remarks.

According to claim 16, the needle has a central lumen therethrough, surrounded by a wall made of the claimed polymer in contact with the lumen. This arrangement can be clearly seen in Fig. 1 of the application.

Palasis et al has been cited to show biocompatible pharmaceutical articles, including needles. These needles can be formed from polymers, including PEEK; however, the teaching of this reference is that certain materials are incompatible with the pharmaceuticals contained therein and PEEK is one of these incompatible materials. Thus, Palasis et al discloses at paragraphs [0028] and [0029]:

> According to another embodiment of the invention, a pharmaceutical article for contact with a pharmaceutically active material is provided. The pharmaceutical article comprises: (a) a lumen comprising

> an incompatible material that acts to substantially reduce the pharmaceutical effectiveness of the pharmaceutically active material upon contact; and (b) a barrier layer disposed between the incompatible material and the pharmaceutically active material, wherein the barrier layer is more compatible with the pharmaceutically active material than is the incompatible material.
>
> In some instances, the incompatible material comprises certain metals, such as stainless steel and nickel-titanium alloys. In other instances, the incompatible material comprises certain polymers, such as polycarbonate, polyimide, poly ether ether ketone (PEEK), nylon and acrylonitrile/butadiene/styrene resin.

Accordingly, the Palasis et al reference teaches that PEEK is incompatible with pharmaceutical materials, and when the wall surrounding the lumen comprises PEEK, a barrier layer between the PEEK and the lumen is required. Such a barrier layer is excluded by the invention as claimed.

Similarly, paragraph [0086] of Palasis et al discloses that PEEK meets structural requirements of needles, but Palasis et al has already disclosed that barrier layers should be used when the pharmaceutical article is formed from PEEK.

Paragraph [0090] does not disclose filled polymers, as is alleged in the Office Action. The materials disclosed in paragraph [0090] are inorganic barrier layers which serve to separate the incompatible materials disclosed (for example PEEK) from the pharmaceuticals. These coatings are disclosed as being formed by CVD and PVD, methods which would not be used to form a filled polymer.

The Office Action states that Palasis et al does not disclose the distributed reinforcement members of the

invention; Webster, Jr. has been cited for this purpose.

Webster, Jr. does not, however, disclose any reinforcing wires *embedded in a polymer*. What is shown in Webster, Jr. is a catheter with a lumen 13, a nylon sleeve 25, an inner wall 22 and an outer wall 30. The inner and outer walls are formed of a flexible polymer such as polyurethane; PEEK is not disclosed.

Between the inner and outer walls is a braided reinforcing mesh 24 comprising two helical braid member 26, made of a material with high modulus of elasticity. The Office Action makes reference to warp members 28, formed of a material with lower modulus of elasticity, such as dacron or nylon. A plurality of parallel warp members are shown in Fig. 2; they are not however embedded in any of the polymer layers, but are disposed between the layers. In order to suggest the invention, Webster, Jr. would need to disclose embedding the warp members in a polymer layer, especially layer 25 which surrounds the lumen. Such an arrangement is not disclosed by Webster, Jr.

Moreover, the invention requires reinforcement wires defining identical center angles so that deformation is avoided during depyrogenation of the needle. Materials such as polyurethane used by Webster, Jr. are not resistant to the depyrogenation temperature of 253°C.

Thus, the invention provides a plastic needle which is depyrogenatable without deformation, and which has sufficient rigidity for penetration of the skin and subcutaneous layers. The problem of avoiding deformation during depyrogentation of plastic needles and maintaining rigidity of the needles is not discussed at all in the art cited in the Office Action to reject the claims.

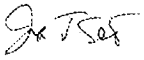
Stawski has been cited to show a syringe with a needle beveled at both ends, a piston, a recipient connector and

other elements of claims 7-15. Stawski does not however cure the defects of Palasis et al and Webster, Jr., as discussed in detail above.

Withdrawal of these rejections is requested.

In view of the foregoing amendments and remarks, Applicants submit that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,



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